AU 3745

# PATENT APPLICATION

## *IN THE UNITED STATES PATENT AND TRADEMARK OFFICE*

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| *Group:* | 3743 | ) |
| *Attorney Docket:* | BER-3.5.009/3714 (13395CON) | ) |
| *Applicant:* | Coffee, R. A. | ) |
| *Title:* | Dispensing Device and Method for Forming Material | ) |
| *Serial No.:* | 09/758,716 | ) |
| *Filed:* | January 11, 2001 | ) |
| *Examiner:* | Lewis, Kim M. | ) |

Certificate Under 37 CFR § 1.10

I hereby certify that this correspondence is being deposited with the United States Postal Service in an envelope addressed to Commissioner for Patents, Box 1450, Alexandria, VA 22313-1450 as "Express Mail Post Office to Addressee".

on February 7, 2005

William B. Richards

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## DECLARATION OF DR. HERBERT S. BRESLER – 37 C.F.R. § 1.132

I, Dr. Herbert S. Bresler of 2610 E. Broad Street, Bexley, Ohio 43209, United States of America, hereby declare:

1. That I have read and understand the present Patent Application and the related Office Action mailed October 7, 2004.

2. I received a B.S. in Biological Sciences and a B.S. in Secondary Science Education, both from the University of Maryland, and a Ph.D. in Immunology and Infectious Diseases from The Johns Hopkins University.

3. My broad experience encompasses diagnostic immunology, biological therapy development, programs in infectious diseases and oncology, and evaluating new matrix materials for tissue engineering. I am also an Adjunct Assistant Professor at The Ohio State University School of Medicine and Public Health, Department of Molecular Virology, Immunology, and Medical Genetics.

4. I am currently Chief Scientist with Battelle Health & Life Sciences, Battelle Memorial Institute, Columbus, Ohio.

5. Prior to joining Battelle, I was Laboratory Director, Laboratory of Immunotherapeutics, the Arthur G. James Cancer Hospital and Research Institute, The Ohio State University, Managing Scientist, Cellco, Inc., Germantown, Maryland, where my work led to the

issuance of U.S. Pat. No. 5,498,537 ("Serum-free Production of Packaged Viral Vector") to Bresler *et al.*, Scientific Director, Biotronic Systems Corp., Scientist, ANTECH Consultants, Inc., and a private consultant.

7. I have examined the Martin reference cited by the Examiner (U.S. Pat. No. 4,043,331). As directed by the Examiner, Martin teaches fibers of "very small diameter" to effect a "high surface area" and "[w]here the dressing is formed from a wettable polymer, blood or serum escaping from the wound tends to penetrate the dressing and the high surface area encourages clotting." (Martin at 2:12-16.) Martin also teaches that "[w]here the dressing is formed from a non-wetting polymer . . . if the interstices between the fibres are sufficiently small . . . tissue fluids, including blood, tend not to permeate the dressing, so that the fluids are retained adjacent to the wound, where clotting will occur." (Martin at 2:18-24.) Also, as indicated by the Examiner, Coffee claims "to provide nuclei or otherwise initiate interactive cellular and/or molecular events in tissue repair." Coffee is different and distinguishable. Martin may first use any suitable polymer that will enable mechanical wetting alone. Or, in the case of a non-wetting polymer, provide small interstices. Thus, Martin is concerned with wettable polymers or small interstices. The quoted recitation of claim 61, in contrast, provides fibres, fibre fragments, or particles which "initiate interactive cellular and/or molecular events". *See*, ¶ [0016] ("to promote essential cell activities, for example, to stimulate dendritic growth, growth factors such as fibroblast growth factor (FGF), epithelial growth factor (EGF), transforming growth factor (TGF) and others that may be used to promote or otherwise control the sequence of events essential to natural tissue repair") and ¶ [0071] (same quote). In addition, Martin teaches only *encouraging* clotting which, in turn, *promotes* tissue repair. The effect of the mat in Martin is, thus, as an *indirect* promoter of tissue repair. The effect of the mat in Martin is to encourage clotting, to stop bleeding, and perhaps, create an *environment* which *may* be favorable to tissue repair. As cited in claim 61, molecular events in tissue repair are initiated *directly* by the fibers, fibrils, or particles. Thus, new tissue is generated, at the molecular level, due to the presence of the formed fiber, fibrils, or particles.

8. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 7 February 2005 By: Herbert S Bresler

Herbert S. Bresler, Ph.D.